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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,666	SHIRAHATA ET AL.	
	Examiner	Art Unit	
	THOMAS A. CONWAY	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Specification

2. The disclosure is objected to because of the following informalities: "Fig 14" is mentioned in the Brief Description of the Drawings section of the specification but is not developed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Specifically, the claim has been amended to include the phrase "in one image" – this limitation of the deformation calculating means calculating "in one image" is not supported in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-5, 7, 11-16 and 18 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For example, claim 1 recites the limitation "the organ region" in lines 8-9 and again in line 13. The Examiner is not sure if these instances of "the organ region" is referring to "the organ region" set by the organ region setting means (ln 2), or "the organ region" whose deformation degree is stored by the reference value storing means (ln 7).

Claim 1 recites the limitation "and/or" in line 12 – the Examiner reads this to mean "and or or" and believes the phrase to also be indefinite.

There are similar issues with claim 11. Claim 11 also recites the limitation "the result" in line 12. There is insufficient antecedent basis for this limitation in the claim.

5. **Claims 2-5, 7 and 12-15 are rejected** for the same reasoning as presented with respect to claim 1 with regards to the recitation of "the organ region":

Claim 2, lines 5 and 11;

Claim 3, ln 3;

Claim 4, lines 4, 5 and 8;

Claim 5, lines 3 and 11;

Claim 7, ln 2;

Claim 12, ln 9;

Claim 13, lines 3-4;

Claim 14, lines 4 and 5;

Claim 15, ln 10;

6. **Claim 1** recites the limitation "the result of comparing" in line 9. There is insufficient antecedent basis for this limitation in the claim.

7. **Claim 2** recites the limitation "the previously calculated organ region" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. What was previously calculated, as best understood by the Examiner, was the "degree of deformation from normal shapes of the organ region", not the "organ region" itself, as proposed by the instant claim's recited limitation.

8. **Claim 2** recites the limitation "the plurality of cross-sectional images" in lines 9 and 12. There is insufficient antecedent basis for this limitation in the claim. The Examiner believes the phrase to refer back to "a plurality of cross-sections of the organ

region" in line 5. The recitation in line 5 does not include the term "image". The Examiner suggests for the sake of clarity, that the Applicant include the term "image" in the phrase in line 5 to read similarly, eg.: "a plurality of cross-sectional images …".

9. **Claim 3** recites the limitation "the deformation degree" in line 2-3. There is insufficient antecedent basis for this limitation in the claim. The Examiner is unsure whether this limitation makes reference to the "deformation calculating means" (claim 1, ln 4), which calculates a "degree of deformation", or makes reference to the "deformation degree" associated with the reference value storing means (claim 1, ln 6).

10. **Claim 4** recites "the deformation degree calculating" in line 2. There is insufficient antecedent basis for this limitation in the claim. The Examiner is unsure whether this limitation makes reference to the "deformation calculating means" (claim 1, ln 4), which calculates a "degree of deformation", or a newly recited deformation degree calculating means associated with "deformation degree" associated with the reference value storing means (claim 1, ln 6).

11. **Claim 5** recites the limitation "the degree of deformation of the cross-sectional images of the hollow viscera" in line 11. There is insufficient antecedent basis for this limitation in the claim.

12. **Claim 7** recites the limitation "the cross-sectional images" in lines 2 and 4. There is insufficient antecedent basis for this limitation in the claim.

13. **Claim 13** recites the limitation "the degree of deformation" in line 3. There is insufficient antecedent basis for this limitation in the claim. The Examiner is unsure whether this limitation makes reference to the "deformation degree calculating step" (claim 11, ln 4), which calculates a "degree of deformation", or a newly recited degree of deformation associated with "deformation degree" associated with the reference value storing step (claim 11, ln 7).

14. **Claim 14** recites "calculates calculating". The Examiner believes this to be a typographical error, repeating the root term "calculate", but as it stands, the phrase is indefinite.

15. **Claim 16** recites the limitation "and/or" in line 3: the Examiner reads this to mean "and or or" and believes the phrase to be indefinite.

16. **Claim 18** recites the limitation "and/or" in lines 3 and 4: the Examiner reads this to mean "and or or" and believes the phrase to be indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows (see also MPEP 2106):

> Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.
>
> When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).
>
> In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

17. **Claims 1-10 are rejected under 35 U.S.C. 101** because the claimed invention is directed to non-statutory subject matter as follows. Claims 1-10 appear to define an apparatus using "means plus function" claim language. However, the specification does not disclose corresponding physical structure associated with each claim element.

Therefore, the claim as a whole appears to be nothing more than a collection of software elements, thus defining functional descriptive material per se.

Functional descriptive material may be statutory if it resides on a "computer-readable medium or computer-readable memory". The claims indicated above lack structure, and do not define a computer readable medium and are thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests:

1. Amending the claims to embody the program on "computer-readable medium" or equivalent; assuming the specification does NOT define the computer readable medium as a "signal", "carrier wave", or "transmission medium" which are deemed non-statutory (refer to "note" below); or

2. Pointing out where the corresponding structure can be found in the specification that would clearly be indicative of a statutory apparatus, in a 112 6th paragraph sense.

Any amendment to the claim should be commensurate with its corresponding disclosure.

Note:

"A transitory, propagating signal ... is not a "process, machine, manufacture, or composition of matter." Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter." (*In re Nuijten*, 84 USPQ2d 1495 (Fed. Cir. 2007)).

Should the full scope of the claim as properly read in light of the disclosure encompass non-statutory subject matter such as a "signal", the claim as a whole would be non-statutory. Should the applicant's specification define or exemplify the computer readable medium or memory (or whatever language applicant chooses to recite a computer readable medium equivalent) as statutory tangible products such as a hard drive, ROM, RAM, etc, **as well as** a non-statutory entity such as a "signal", "carrier wave", or "transmission medium", the examiner suggests amending the claim to *include* the disclosed tangible computer readable storage media, while at the same time *excluding* the intangible transitory media such as signals, carrier waves, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al. (U.S. Pub. No.: 2001/0043729 A1,"Giger").

18. **Regarding claims 1 and 11**, Giger discloses a medical image diagnosis support device and method, comprising: an organ region setting means for setting organ regions (¶ [0024]: "automated segmentation of mass regions" – See also ¶ [0030]) in medical images obtained by a medical imaging device (Claim 1, ln 1-3); a deformation calculating means for calculating in one image a degree of deformation from normal shapes of the organ regions set by the organ region setting means (¶ [0030]: calculation of likelihood of malignancy of an unknown case – See also claim 1); a reference value storing means for storing a deformation degree of an organ region as a reference value (¶ [0030]: calculation of likelihood of malignancy of known case – See also claim 1); a lesion detecting means for detecting existence of lesion of the organ region from the result of comparing the reference value stored by the reference value storing means with the degree of deformation being calculated by the deformation degree calculating means (¶ [0030]: similarity index is calculated comparing the unknown case to the known case and the result is achieved by presenting "similar" cases – See also claim 1); and an informing means for visually and/or auditorily informing the existence of the lesion of the organ region detected by the detecting means (Claims 1-4: "display the image data" and, visual "indicator" associated with a malignancy).

19. **Regarding claims 3 and 13**, Giger discloses the medical image diagnosis support device and method of claims 1 and 11. Giger further discloses wherein the reference value storing means stores a plurality of templates according to the deformation degree of the organ region (¶ [0011]: feature characteristics associated with a known image data set).

20. **Regarding claims 6 and 16**, Giger discloses the medical image diagnosis support device and method of claims 1 and 11. Giger further discloses wherein the informing means informs the existence of the lesion visually by displaying the lesion through colors or movement in displayed images (Claim 4: displaying colored borders associated with malignancy).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 5, 7, 9, 12, 14, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Greenberg et al. (US 6,301,498 B1: "Greenberg").

22. **Regarding claims 2 and 12**, while Giger discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose a bifurcation detecting means for detecting bifurcation of the previously calculated organ region; a means for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting means; and a distance calculating means for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sectional images, and wherein the lesion detecting means detects the existence of the lesion in the organ region based on the shortest distance of

the opposed peripheral portion between the plurality of the cross-sectional images, calculated by the distance calculating means.

Greenberg discloses a bifurcating detecting means for detecting bifurcation of the previously calculated organ region (Col. 10, lines 17-21); a means for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting means (Fig. 6d); and a distance calculating means for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sectional images (Col. 2, lines 36-42), and wherein the lesion detecting means detects the existence of the lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sectional images calculated by the distance calculating means (Col. 3, lines 45-47).

Giger's disclosure was detailed with specific reference to mammographic details but as he mention in ¶ [0070], the elements of his invention can be implemented for other medical images, such as chest radiography, ultrasound, and magnetic resonance imaging. Acknowledgement that these other types of imaging is acceptable, suggests that the details of that imaging could encompass terms or structures not explicitly mentioned in the Giger patent, such as, "organ", "bifurcation", "viscera" and "lumen".

Since examination of internal organs and other localized structures are available as per Giger's disclosure, then the examination of these would be specific to their featured characteristics (See Giger, claim 1). Since lesions, stenosis and the like are often characterized by constriction or narrowing of a structure under inspection (specific to Greenberg's examination of arteries), examination of the geometric attributes of the

suspect region would be an obvious endeavor (Greenberg, Col. 3, lines 18-25). Giger doesn't specifically mention using cross-sectional images since his invention was dealing with mammography, but examination of other internal organs was known in the art at the time of the invention, to frequently deal with cross-sectional images or "slices".

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Giger, a means for detecting bifurcation of the previously calculated organ region; a means for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting means; and a distance calculating means for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sectional images, and wherein the lesion detecting means detects the existence of the lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sectional images, calculated by the distance calculating means, as suggested by Greenberg, in order to examine other internal structures other than mammaries.

23. **Regarding claims 4 and 14**, while Giger discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose wherein the deformation degree calculating means includes: a cross-sectional image calculating means for calculating cross-sectional images that are orthogonal to axial direction of the organ region; and an extracting means for extracting a lumen and an exterior of the organ region from the cross-sectional images calculated by the cross-sectional image

calculating means; and calculates a degree of deformation of the lumen and the exterior of the organ region extracted by the extracting means.

Greenberg discloses a cross-sectional image calculating means for calculating cross-sectional images that are orthogonal to axial direction of the organ region (Fig. 5A); and an extracting means for extracting the lumen and an exterior of the organ region from the cross-sectional images calculated by the cross-sectional image calculating means (Fig. 5E); and calculates a degree of deformation of the lumen and the exterior of the organ region extracted by the extracting means (Col. 8, lines 40-54)

Therefore, for the same reasons as stated in the presentation of claims 2 and 12 (see above), it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Giger, the means as outlined by Greenberg, for calculating the cross-sectional images that are orthogonal to axial direction of the organ region; and an extracting means for extracting the lumen and the exterior of the organ region from the cross-sectional images being calculated from the cross-sectional image calculating means; and calculates the degree of deformation of the lumen and the exterior of the organ region being extracted by the extracting means, in order to examine other internal structures other than mammaries.

24. **Regarding claims 5 and 15**, while Giger discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose an extracting means for extracting a hollow viscera from the organ region; a notable region setting means for setting a notable region of the hollow viscera extracted by the extracting means; and a

means for creating cross-sectional images of the hollow viscera extracted by the extracting means based on the notable region set by the notable region setting means, and wherein the lesion detecting means detects the existence of the lesion of the organ region based on the degree of deformation of the cross-sectional images of the hollow viscera.

Greenberg discloses an extracting means for extracting a hollow viscera from the organ region (Col. 5, lines 11-30); a notable region setting means for setting a notable region of the hollow viscera extracted by the extracting means (Col. 9, lines 19-24); and a means for creating the cross-sectional images of the hollow viscera extracted by the extracting means based on the notable region set by the notable region setting means (Col. 9, lines 14-18), and wherein the lesion detecting means detects the existence of the lesion of the organ region based on the degree of deformation of the cross-sectional images of the hollow viscera (Col. 19, lines 13-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Giger, a means for extracting the hollow viscera out of the organ region being set by the organ region setting means; a notable region setting means for setting the notable region of the hollow viscera being extracted by the extracting means; and a means for creating the cross-sectional images of the hollow viscera being extracted by the extracting means based on the notable region being set by the notable region setting means, and wherein the lesion detecting means detects the existence of the lesion of the organ region based on the deformation degree of the cross-sectional images of the hollow

viscera being created by the creating means, as suggested by Greenberg, in order to facilitate the examination of other internal organs other than a mammary.

25. **Regarding claims 7 and 17**, Giger discloses the medical image diagnosis support device and method according to claims 6 and 16. Giger also discloses a visual presentation that highlights the lesion candidate portions being detected by the lesion detecting means on the images (Claim 4), but fails to disclose wherein the visual presentation is executed by displaying the cross-sectional images of the organ regions, and by highlighting lesion candidate portions detected by the lesion detecting means on the cross-sectional images.

Greenberg discloses wherein the visual presentation is executed by displaying the cross-sectional images of the organ regions, and by highlighting lesion candidate portions detected by the lesion detecting means on the cross-sectional images (Claim 11: means for expressing the X-ray intensity for each X-ray image as lumen functions across an artery cross section).

Greenberg's teaching allows for discriminating the details of a region of interest in such a way that would facilitate identification of lesions of other organs other than mammaries. Lesions and stenosis of organs have geometric characteristics that a cross-sectional image would present in a more obvious manner. Highlighting the relevant areas in a cross-sectional image would even more so draw the attention of an operator to the area of interest. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply

the teachings of Greenberg to Giger in order to facilitate identification by an operator of the existence of lesions in a cross-sectional image.

26. **Regarding claims 9 and 19**, Giger discloses the medical image diagnosis support device and method according to claims 1 and 11, but fail to disclose a cross-section extracting means for extracting cross sections from a feature quantity of a hollow viscera on the medical images obtained by the medical imaging device; a physical quantity calculating means for calculating a physical quantity including radius, degree or circularity, and gravity point of the hollow viscera on the hollow viscera cross-sections extracted by the extracting means; an ROI calculating means for calculating a region of interest based on the physical quantity calculated by the physical quantity calculating means; a 3-dimensional image creating means for creating 3-dimensional images of the hollow viscera from the medical images including the cross sections of the hollow viscera extracted by the cross section extracting means within the region of interest calculated by the ROI calculating means; and an image displaying means for displaying the 3-dimensional images created by the 3-dimensional image creating means.

Greenberg discloses a cross-section extracting means for extracting cross sections from a feature quantity of the hollow viscera on the medical images obtained by the medical imaging device (Co1.5, lines 30-33: Greenberg does this using lumen functions.); a physical quantity calculating means for calculating a physical quantity including radius, degree of circularity, and gravity point of the

hollow viscera on the hollow viscera cross-sections extracted by the extracting means (Col. 3, lines 19-25: analysis of a cross-sectional area could produce radius, degree of circularity as well as gravity point (understood to be a center point)) ; an ROI calculating means for calculating a region of interest based on the physical quantity calculated by the physical quantity calculating means (col. 3, lines 26-30); a 3-dimensional image creating means for creating 3-dimensional images of the hollow viscera from the medical images including the cross sections of the hollow viscera extracted by the cross section extracting means within the region of interest being calculated by the ROI calculating means (Claim 1 : reconstructing the lumen functions to create a three-dimensional image); and an image displaying means for displaying the 3-dimensional images created by the 3-dimensional image creating means (Abstract: lines 7-8; see also Fig. 3A).

As Giger mentions, his method of mammary examination can also be used to examine other non-mammary, thoracic elements. Greenberg's method does, using appropriate terms and methods, represents analysis and display of results in a non-mammary, thoracic examination. Analysis of organ and vessel shapes can indicate relevant conditions, such as lesions and stenoses. Cross-sectioning areas of interest in order to develop dimensional data with regards to an organ or vessel would facilitate an operator to visually identify possible lesions or stenoses. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Greenberg to Giger in order to calculate

dimensional data of an area of interest by which an operator might identify lesions or stenoses.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Heilbrun et al. (U.S. Pub. No.: 20010039421 A1,"Heilbrun").

27. **Regarding claims 8 and 18**, Giger discloses all the limitations of claims 1 and 11. Giger further discloses informing the existence of a lesion to an examiner (Claim 4) but fails to disclose wherein the informing means informs the existence of the lesion auditorily by outputting it through voices and sounds, or a variance of the voices and sounds.

Heilbrun discloses informing auditorily by outputting it through voices and sounds (Page 8, lines 6-10). While Heilbrun's notification is regarding the position of the operative portion of an instrument relative to structures of interest, it is the goal to notify the operator of relevant information that is important. In Heilbrun's invention, the relevant information that needs to be related to the examiner is the position of the operative portion of an instrument, while in Giger's invention, the relevant information is the notification of the location of a lesion. Giving auditory notification to an operator of some type of event which is in the interest of the operator to notice is an obvious method that is used in many arts. A voice alert is an organized set of sounds relating to speech, therefore, the use of voice in itself is the use of sound

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device and method of Giger, the step of informing auditorily by outputting it through voices and sounds as suggested by Heilbrun, in order to more effectively draw the attention of an operator to a specific area of relevance, such as the existence of a lesion.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger and Greenberg in view of Knoplioch (U.S. Patent Number: 6643533, "Knoplioch").

28. **Regarding claims 10 and 20**, while the combination of Giger and Greenberg disclose the limitations of claims 9 and 19, they fail to disclose the limitations of claims 10 and 20.

Knoplioch discloses a center-line calculating means for calculating a center line of the hollow viscera based on the gravity point of the hollow viscera cross sections calculated by the physical quantity calculating means (Col. 6, lines 31-34), wherein the image display means displays the center line calculated by the center-line calculating means together with the 3-dimensional images being created by the 3-dimensional image creating means (Col. 3, lines 22-24; with reference to Fig. 4 - See also: Col. 5, lines 18-23). Knoplioch's teaching allows for geometrical display of organs under scrutiny with reference to a centerline which would facilitate critical analysis of any

objects of interest. Abnormalities of organs and vessels are often easily noticed with reference to shape and utilizing a reference plane or line such as a centerline, would facilitate determination of abnormalities which might be considered relevant.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method and device of Giger, a center-line calculating means for calculating a center line of the hollow viscera based on the gravity point of the hollow viscera cross sections calculated by the physical quantity calculating means, wherein the image display means displays the center line calculated by the center-line calculating means together with the 3-dimensional images being created by the 3-dimensional image creating means, as suggested by Knoplioch, in order to facilitate visual determination by an operator of displayed abnormalities which might be considered relevant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swett et al. (Expert system-controlled image display, August 1989 Radiology, 172, pp 487-493), Huo et al. (Analysis of spiculation in the computerized classification of mammographic masses, Med. Phys., Vol 22, Issue 10, pp 1569-1579), Declerck et al. (Automatic registration and alignment on a template of cardiac stress and rest SPECT images, Mathematical Methods in Biomedical Image Analysis Proceedings on, 1996, pp212-221) all disclose an image

extraction method which identifies abnormalities in association with reference templates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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